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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,170	02/04/2002	Paul Douglas Clarke	TPP 31435	4789

7590 06/27/2003

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Suite 850
1615 L Street NW
Washington, DC 20036

EXAMINER

COE, SUSAN D

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 06/27/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/031,170

Applicant(s)

CLARKE, PAUL DOUGLAS

Examiner

Susan Coe

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 February 2003 and 14 April 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 36-55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36-55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

1. The amendments filed February 6, and April 14, 2003, have been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior Office action.
2. Claims 1-35 have been cancelled.
3. Claims 36-55 have been added and are examined on the merits.

Claim Rejections - 35 USC § 102

4. Claims 36-40 and 44-46 are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat. No. 5,298,250 for the reasons set forth on pages 4 and 5 of the previous Office action.

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that the reference does not teach a composition of PMD and a carrier which is suitable for insertion into the human body; however, US '250 teaches using various carriers, such as water, that can be used as the carrier for PMD (see columns 8-10). Many of these carriers can be inserted into the human body without toxicity. Thus, even if US '250 does not specifically teach inserting the composition into the body, the composition meets the limitations of applicant's claims.

5. Claims 36-40 and 44-46 are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat. No. 5,698,209 for the reasons set forth on page 5 of the previous Office action.

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that the reference does not teach a composition of PMD and a carrier which is suitable for insertion into the human body; however, US '209 teaches using various carriers, such as water, that can be used as the carrier for PMD

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(see column 2, lines 4-54). Many of these carriers can be inserted into the human body without toxicity. Thus, even if US '209 does not specifically teach inserting the composition into the body, the composition meets the limitations of applicant's claims.

Claim Rejections - 35 USC § 103

6. Claims 41-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No 5,298,250 for the reasons set forth on pages 6 and 7 of the previous Office action.

Applicant argues against this rejection in combination with the argument against the 102(b) rejection over this reference. Therefore, the rejection is considered valid for the reasons stated above and in the previous Office action.

7. Claims 41-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No 5,298,250 for the reasons set forth on page 7 of the previous Office action.

Applicant argues against this rejection in combination with the argument against the 102(b) rejection over this reference. Therefore, the rejection is considered valid for the reasons stated above and in the previous Office action.

8. Claims 36-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shahi et al. (Current Science (Bangalore) (March 1999), vol. 76, no. 6, pp. 836-839) for the reasons set forth on pages 7 and 8 of the previous Office action.

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that the reference does not teach combining the PMD containing extract with a carrier. However, it is well known in the art to add carriers to

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pharmaceutically active substances. Therefore, it is considered an obvious modification of the reference to formulate the PMD containing extract in the manner claimed by applicant.

In addition, applicant argues that the reference does not teach that the composition is designed to be used internally. However, carriers that are “suitable for insertion into the human body” are well known carriers. Therefore, it would be obvious to create a composition that contains the PMD containing extract and a carrier that meets this limitation.

9. Claims 36-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muanza et al. (Int. J. Pharmacog (1994), vol. 32, no. 4, pp. 337-345) for the reasons set forth on page 8 of the previous Office action.

All of applicant’s arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that the reference does not teach combining the PMD containing extract with a carrier. However, it is well known in the art to add carriers to pharmaceutically active substances. Therefore, it is considered an obvious modification of the reference to formulate the PMD containing extract in the manner claimed by applicant.

In addition, applicant argues that the reference does not teach that the composition is designed to be used internally. However, the reference shows that the composition has activity against microorganisms that can cause internal infections. Therefore, a person of ordinary skill in the art would be motivated to use the reference composition to treat these infections. In addition, carriers that are “suitable for insertion into the human body” are well known carriers. Therefore, it would be obvious to create a composition that contains the PMD containing extract and a carrier that meets this limitation.

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10. No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

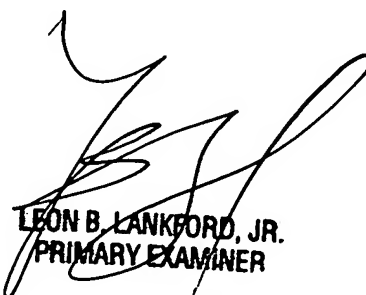
A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (703) 306-5823. The examiner can normally be reached on Monday to Thursday from 8:00 to 5:30 and on alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (703) 306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Susan Coe, Examiner
June 26, 2003



LEON B. LANKFORD, JR.
PRIMARY EXAMINER